Indiana State Department of Health

LTC Newsletter

LTC & ICF/MR HOMES

Volume 6, Issue 1 *Division of Long Term Care Publication* *January 2006*

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2005 Year In Review

A look at data from 2005 reveals that 27 new long-term care facilities emerged in Indiana last year, of which 8 are certified comprehensive care and 19 are licensed residential care. Conversely, 2005 saw the closure of 5 long-term care facilities. 29 long-term care facilities changed ownership last year.

Survey data for long-term care facilities reveals that Division surveyors conducted 7 initial certification surveys, 485 recertification surveys and 547 relicensure surveys in nursing homes and residential care facilities in 2005. In addition, surveyors conducted 1,514 complaint investigation surveys. 51 federal recertification surveys were deficiency-free. However, 434 recertification surveys required follow-up visits. As a result, surveyors completed a total of 1,255 follow-up surveys for the year. The grand total number of surveys conducted in long-term care facilities in 2005 was 3,266. Immediate jeopardy was found in 56 of these surveys, and 79 surveys had findings of substandard quality of care.

2005 saw the addition of 6 new Intermediate Care Facilities for the Mentally Retarded (ICFs-MR), but saw the closure of 2 facilities for the developmentally disabled, including Muscatatuck State Developmental Center. ICF-MR surveyors conducted, in addition to the 6 initial certification and state licensure surveys, 522 recertification and relicensure surveys and 88 complaint investigation surveys. 874 follow-up surveys were conducted in ICFs-MR, bringing the total number of surveys to 1490. Immediate jeopardy was found during 18 ICF-MR surveys in 2005.

To see how these numbers compare to 2004, see the table on page 5.

Elizabeth Honiotes Appointed as CMS Region V Indiana Branch Manager

Elizabeth Honiotes was appointed as the Division of Survey and Certification branch manager for Indiana and Wisconsin at the Centers for Medicare and Medicaid Services (CMS) Region V office in Chicago, Illinois. Honiotes stepped into the position held by Marilyn Hirsch, who was recently promoted to the position of Branch Manager of Survey and Coordination Branch.

Ms. Honiotes began her federal career with CMS (formerly the Health Care Financing Administration) in 1993 in the Division of Survey and Certification (formerly Health Standards and Quality). She has experience as a Federal Surveyor, a State Leader (survey) and a Principal Program Representative (certification and enforcement).

In the past 2 years, Ms. Honiotes was a branch manager in the CMS Division of Medicaid and Children's Health. She returned to the Division of Survey and Certification in October 2005.

Ms. Honiotes' interest in long term care began in high school when she was a regular volunteer at a local nursing home. She is a registered nurse with experience from pediatrics to geriatrics in various clinical settings including long term care, home health, hospital, and outpatient clinics. Prior to coming to CMS, she was a manager in the health quality division of a peer review organization.

Honiotes works with Heather Lang, who became Indiana's CMS Principal Program Representative in January 2005.

GAO Report Cites Weakness in Nursing Home Fire Safety Standards

A study of nursing home fires conducted in 2004 by the U.S. Government Accountability Office (GAO) concluded that nearly 30 percent of nursing facilities nationwide lack appropriate fire safety standards. Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversight, GAO-04-660, report released (7/16/2004). The agency was asked by the Centers for Medicare & Medicaid Services to examine nursing home fire safety standards after 31 residents died in 2003 in fires in Hartford, Connecticut, and Nashville, Tennessee.

According to the Coalition to Protect America's Elders, which published an August 6, 2004 article on the GAO's findings, the report called for a review of the appropriateness of not requiring all nursing homes to have sprinklers and smoke detectors.

The GAO study revealed that about 2,300 of the nation's 16,000 nursing homes reported structural fires each year from 1994 through 1999, and that about five fire-related deaths per year were reported nationally during the same time period. The GAO report further revealed that the death toll in 2003 was considerably higher.

The report attributed the leading causes of nursing home fires to cooking-related fires and laundry room dryers. Resident deaths, however, were largely due to smoking-related fires.

The GAO suggested in its report that government regulators need to re-examine federal safety standards that do not require sprinklers in older nursing homes that were constructed with non-combustible materials.

Both the Hartford and Nashville homes, built respectively in 1970 and 1967, were allowed to operate without sprinklers "even though they have been proven very effective in reducing the number of multiple deaths from fires," the GAO said.

The agency further explained that federal standards do not require smoke detectors in most nursing homes. The report noted that investigators of the Hartford and Nashville fires suggested that the lack of smoke detectors in resident rooms, where the fires reportedly started, might have delayed staff response and activation of the facilities' fire alarms.

The report concluded that federal and state agencies need to take a more aggressive role in ensuring compliance with fire safety standards, but acknowledged that the cost to retro-fit older facilities with sprinkler systems has been a "barrier" to the government requiring them in all nursing homes nationwide.

The July 16, 2004 GAO report may be viewed in its entirety at the following internet address: http://www.gao.gov/new.items/d04660.pdf.

CHANGES IN THE QMA RULES 412 IAC 2-1-1

On November 14, 2005, changes in the Qualified Medication Aide (QMA) rules became effective. Important changes relate to in-service education requirements and fee submission, the recertification and reinstatement processes. Also for initial QMA certification, the renewal period begins on the certification effective date and concludes on the last day of the month of February of the following year. All QMA certifications expire annually on March 31. Required in-service education forms and fees must be submitted to the Indiana State Department of Health by the last day of February. A copy of the new rules can be obtained at http://www.in.gov/legislative/iac/title412.html. Please contact Nancy Adams, R.N., at 317-233-7480, or Nancy Gilbert at 317-233-7616 with any questions.

Suzanne Hornstein Elected President of the Association of Health Facility Survey Agencies

Suzanne Hornstein, MSW, Director of the Indiana State Department of Health's Division of Long Term Care, was recently elected to serve as President of the Association of Health Facility Survey Agencies (AHFSA).

AHFSA is a national association of state survey agencies, whose mission is to strengthen the role of its member agencies in advocating, establishing, overseeing and coordinating health care quality standards that will assure the highest practicable quality of health care for all state and federally regulated health care providers. The association meets these goals through member advocacy to various organizations and agencies; through the gathering, communicating and exchanging of health related information; through advice and recommendation to the Centers for Medicare and Medicaid Services (CMS), Association of State and Territorial Health Officials, Inc. (ASTHO) and other health agencies, associations and entities; through helping to improve the quality of state and territorial health facility survey programs; and, through the professional development of its members.

Prior to her election as President in October 2005, Hornstein was President Elect for a one-year term. From October 2003 through October 2004, Hornstein served AHFSA as Vice President.

For more information about AHFSA, visit http://www.ahfsa.org.

UPDATING CNAs...

If you are having problems with updating your CNAs using the CD ROM provided by the ISDH, or you have misplaced the CD ROM, you may call the ISDH Nurse Aide Registry at 317/233-7639 and request a duplicate.

'Almost Home' Documentary to Air on PBS

'Almost Home' delivers a dramatic and surprising story about aging that grips you from the start, never flinches from reality, and offers hope where many think there is none.

'Almost Home' is a feature-length, cinema verité film that rescues the real stories of aging from an exile of denial.

Shot over the course of a year at a retirement community in America's Midwest, 'Almost Home' follows one couple bonded by their struggle with Alzheimer's and another divided by the challenges of Parkinson's; children who are torn between caring for their parents and caring for their own children; nursing assistants who must do unsavory work for poverty wages while juggling precarious lives at home; healthy elders who fear the day they may have to move to the dreaded nursing home; and a visionary nursing home director who feverishly works to alleviate such fear by transforming the impersonal, regimented hospital-like institution into a warm "home" that promotes autonomy and inspires independence rather than fear.

'Almost Home' airs February 21, 2006, on the national PBS series INDEPENDENT LENS. Please check local listings for times. For more information, visit the 'Almost Home' web site, http://www.almosthomedoc.org/.

- Submitted by
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Health Care Excel
Indiana Medicare Quality Improvement Organization (QIO) 812-234-1499, Ext. 296

FAMILIAR FACES, NEW PLACES

The Indiana State Department of Health (ISDH) recently welcomed familiar faces to new positions.

Chris Greeney accepted the position of ICF-MR medical surveyor supervisor for the northern half of Indiana in November 2005. Greeney is no stranger to the ISDH, though. He began his employment with the State of Indiana in 1994 as a medical surveyor. Greeney was promoted to the ICF-MR medical surveyor supervisor position for the southern half of the state in 1998. He left state employment in 2002 to pursue private interests, but returned to state employment in 2003 as a medical surveyor.

Greeney has worked in the social services field since 1985, having been employed both in the fields of service to individuals with mental retardation and developmental disabilities as well as programs providing services to adolescents with severe emotional problems and adults with mental illness. His experience includes serving as a direct care staff; creation, development and implementation of intensive outpatient behavioral health programs for adolescents and adults; residential and sheltered workshop staff supervision and management; and serving as a Qualified Mental Retardation Professional and as a Program Services Director.

Greeney earned a Bachelor of Arts degree in Sociology from Indiana University South Bend, and a Master of Business Administration degree from Bethel College in Mishawaka, Indiana.

Meanwhile, Brenda Meredith, RN, who served in the ICF-MR program as quality review and medical surveyor supervisor for northern Indiana for the past three years has accepted the position as Long Term Care Area Supervisor for the northeastern portion of Indiana.

Meredith began her nursing career working in a hospital for approximately thirteen years as a med-surg nurse, eventually increasing her responsibility by becoming the director of outpatient services. Meredith's focus shifted to long term care when she accepted a position as a director of nursing for a long term care facility for an additional six years, and a subsequent MDS coordinator position for two years.

In July 1999, Meredith began working for the ISDH as a public health nurse surveyor, until May of 2003, when she transitioned to the Division's ICF-MR program.

Meredith holds an Associate of Nursing degree from Indiana University Kokomo, and has been a licensed nurse since 1978.

The ISDH welcomes these familiar faces to their new positions of responsibility, and wishes them well in the coming years!

INCIDENTS INVOLVING CNAs

The Indiana State Department of Health (ISDH) requests that all incidents involving CNAs submitted to the ISDH include the CNAs Nurse Aide Registry number.

The ISDH requests CNA registry numbers to help distinguish between individuals with common names (e.g., Jane Smith), and to help protect individuals social security numbers from being unnecessarily revealed. Thank you for your cooperation.

IN SHAPE INDIANA
Governor Mitch Daniels

In an effort to help Hoosiers make healthy choices by linking them to valuable resources and encouraging them to improve their health and well-being, Governor Mitch Daniels launched INShape Indiana. The program's interactive website serves as a clearinghouse of information on nutrition, physical fitness and smoking cessation. Interested Hoosiers can register with INShape Indiana, which allows them to conduct a brief update every two weeks to help them track their progress toward healthier living.

"By improving your own health and that of your family, you are not only helping yourself, but contributing to a healthier Indiana," said Governor Daniels in the introduction to the program's website. "This public health problem is one that we can all do our part to reverse," added Daniels.

In keeping with this philosophy, the Division of Long Term Care would like to highlight an INShape Indiana initiative in each upcoming issue.

In this, the first of our INShape Indiana updates, the focus is on Smoking Cessation.

According to the American Lung Association, "Smoking-related diseases claim an estimated 430,700 American lives each year. Smoking costs the United States approximately $97.2 billion each year in health-care costs and lost productivity. It is directly responsible for 87 percent of lung cancer cases and causes most cases of emphysema and chronic bronchitis."

Let's drive the point home. INShape Indiana reports that the leading cause of preventable death in Indiana is tobacco use. The Indiana Tobacco Prevention and Cessation agency (ITPC) numbers Indiana tobacco-related deaths at more than 9700 each year. "Indiana currently ranks 7th among all states in adult smoking prevalence," and, as of 1998, Indiana had smoking attributable direct medical expenditures in excess of $1, 627,000,000, reports the ITPC.

While the best prevention for tobacco-related illnesses is to never start smoking, it's never too late to quit. The ITPC encourages smokers that health begins to improve almost immediately after quitting, and health benefits increase steadily over time after quitting.

For more information on smoking cessation, visit the INShape Indiana website at http://www.in.gov/inshape/tobacco/. Your health, or the health of someone you love, may depend on it.

POTENT NEW STRAIN OF BACTERIUM CIRCULATING IN HOSPITALS AND NURSING HOMES

In July 2005, the Centers for Disease Control and Prevention (CDC) reported the emergence of a new strain of a spore-forming, gram positive anaerobic bacteria known as *Clostridium difficile*, or *C. diff*, more virulent than its antecedent, with the ability to produce greater quantities of toxins that can damage intestinal organs. The CDC has found that in the past 2 years, several states have reported an increase in *C. diff* cases, noting more severe disease and an associated increased risk in mortality.

In a December 29, 2005 article by the Cleveland, Ohio newspaper, 'The Plain Dealer,' recent outbreaks in Ohio have spurred the Ohio Department of Health to require all hospitals and long-term care facilities in that state effective January 1, 2006 to submit weekly reports on cases of *C. diff*.

Pam Pontones, Director of Surveillance and Investigation with the Indiana State Department of Health's Epidemiology Resource Center, says that the ISDH is taking a "watchful waiting" approach, monitoring any reporting that comes into the local health departments, looking at literature from the CDC and other resources, and watching to see what other states are doing.

According to the CDC, individuals most at risk for *C. diff* are those with extended lengths of stay in healthcare settings, those with serious underlying illness, immunocompromising conditions, gastrointestinal surgery/manipulation, advanced age, and antibiotic exposure. Symptoms include watery diarrhea, fever, loss of appetite, nausea and abdominal pain or tenderness.

C. diff is transmitted, according to a July 2005 information release to healthcare providers, to patients "mainly via the hands of healthcare personnel who have come into contact with a... surface or item," contaminated with feces containing *C. diff* spores.

The CDC encourages healthcare facilities to utilize infection control strategies such as appropriate hand hygiene to prevent cross contamination between patients; contact precautions for patients with known or suspected C. difficile-associated disease, to include possible isolation, the use of gloves during patient care, the use of gowns if soiling of clothes is likely, and dedicated equipment whenever possible; and aggressive environmental cleaning and disinfection strategies.

Pontones encourages facilities not to "write-off" suspicions of *C. diff*, but to report any outbreaks of diarrhea to their local health department for further investigation.

LTC Facilities for 2004

New Facilities	Closures	Changes of Ownership
15	12	23
Initial Surveys	**Recertification Surveys**	**Complaint Investigations**
5	512	1421
Revisits	**Total Surveys**	**Deficiency-Free Recertification Surveys**
1123	3061	101
Surveys with IJ	**Surveys with SQC**	
30	44	

ICF-MR Facilities for 2004

New Facilities	Closures	Changes of Ownership
4	9	0
Initial Surveys	**Recertification Surveys**	**Complaint Investigations**
4	517	94
Revisits	**Total Surveys**	**Deficiency-Free Recertification Surveys**
710	1325	
Surveys with IJ		
11		

Top 10 LTC Deficiencies 2005

1. F0324 Accidents
2. F0281 Resident Assessment
3. F0309 Quality of Care
4. F0157 Notification of Rights and Services
5. F0514 Administration
6. F0314 Pressure Sores
7. F0371 Sanitary Conditions-Food Prep & Service
8. F0253 Housekeeping/ Maintenance
9. F0323 Accidents
10. F0441 Infection Control

CMS Launches National Provider Identification Web Page

CMS is pleased to announce a redesigned CMS web page dedicated to providing all the latest NPI news for health care providers! Visit http://www.cms.hhs.gov/NationalProvIdentStand/ on the web. This page also contains a section for Medicare Fee-For-Service (FFS) providers with helpful information on the Medicare NPI implementation. A new fact sheet with answers to questions that health care providers may have regarding the NPI is now available on the web page; bookmark this page as new information and resources will continue to be posted. For more information on private industry NPI outreach, visit the Workgroup for Electronic Data Interchange (WEDI) NPI Outreach Initiative website at http://www.wedi.org/npioi/index.shtml on the web.

Did You Know?

In 2005, the Division of Long Term Care received 164 Informal Dispute Resolution requests, with a total of 287 deficiencies disputed.

Of these, 70.03% resulted in no change, 2.09% resulted in a change in scope and severity of deficiency, 5.57% resulted in a deletion of deficiency, 12.54% resulted in the removal of examples or other wording changes, and 9.76% of the requests for IDR were withdrawn.

Top 10 ICF-MR Deficiencies 2005

1. W0249 Program Implementation
2. W0149 Staff Treatment of Clients
3. W0104 Governing Body
4. W0227 Individual Program Plan
5. W0154 Staff Treatment of Clients
6. W0263 Program Monitoring & Change
7. W0369 Drug Administration
8. W0153 Staff Treatment of Clients
9. W0440 Evacuation Drills
10. W125 Protection of Clients rights

Indiana State Department of Health

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Indiana State Department Of Health
Division of Long Term Care

TELEPHONE GUIDE

Arranged alphabetically by subject

All are Area Code 317

SUBJECT	CONTACT PERSON	EXTENSION
Administrator/DON, Facility Name/Address Changes	Seth Brooke	233-7794
Bed Change Requests (Changing/Adding Licensed Bed/Classifications)	Seth Brooke	233-7794
CNA Registry	Automated	233-7612
CNA Investigations	Zetra Allen	233-7772
CNA/QMA Training	Nancy Adams	233-7480
Director, Division of Long Term Care	Suzanne Hornstein	233-7289
Enforcement & Remedies	Stephen Upchurch	233-7613
Facility Data Inquiries	Sarah Roe	233-7904
FAX, Administration		233-7322
Incidents/Unusual Occurrences	Fax Voicemail Other	233-7494 233-5359 233-7442
Informal Dispute Resolution	Susie Scott	233-7651
License/Ownership Verification Information	Seth Brooke	233-7794
License Renewal	Seth Brooke	233-7794
Licensed Facility Files (Review/Copies)	Darlene Jones	233-7351
Licensure & Certification Applications/Procedures (for New Facilities and Changes of Ownership)	Seth Brooke	233-7794
Life Safety Code	Rick Powers	233-7471
MDS/RAI Clinical Help Desk	Debbie Beers	233-4719
MDS Technical Help Desk	Technical Help Desk Staff	233-7206
Monitor Program	Debbie Beers	233-7067
Plans of Correction (POC), POC Extensions & Addenda	Area Supervisors	See Below
Plans & Specifications Approval (New Construction & Remodeling)	Dennis Ehlers	233-7588
Reporting	Tom Reed	233-7541
Rules & Regulations Questions	Debbie Beers	233-7067
Survey Manager	Kim Rhoades	233-7497
Transfer/Discharge of Residents	Seth Brooke	233-7479
Unlicensed Homes/Facilities	Karen Smith	233-7709
Waivers (Rule/Room Size Variance/ Nursing Services Variance)	Seth Brooke	233-7794
Web Site Information	Sarah Roe	233-7904

AREA SUPERVISORS

Area 1	Judi Navarro	233-7617
Area 2	Brenda Meredith	233-7321
Area 3	Brenda Buroker	233-7080
Area 4	Zetra Allen	233-7772
Area 5	Karen Powers	233-7753
Area 6	Pat Nicolaou	233-7441
Life Safety Code	Rick Powers	233-7471
ICF/MR North	Chris Greeney	233-7894
ICF/MR South	Steve Corya	233-7561

MDS Coordinators, Take Note!

RAI User's Manual

December 2005 Update:
http://www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS20Update200512.pdf

Appendix A:
http://www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS202005AppendixA.pdf

November 2005 Update:
http://www.cms.hhs.gov/NursingHomeQualityInits/20_NHQIMDS20.asp#TopOfPage
(NOTE: Zip File is at bottom of page)

August 2005 Update:
http://www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS20Updated200508.pdf

Changed Dehydration RAP with RAP version 1.02 (12/07/05):
https://www.qtso.com/download/mds/Chgd_Dehydr_RAPwith_RAP_Ver_102_(v1).pdf

MDS Guides and Manuals

https://www.qtso.com/mdsdownload.html

The following are at the bottom of the page.

Reports Version 1.0 (09/12/2005)

LTC Facility User's Guide Version 7.4 (11/20/2005)

Validation Report Messages and Description Version 7.4 (11/20/05)

CMS ANNOUNCES REDESIGNED WEBSITE IS NOW AVAILABLE

The Centers for Medicare & Medicaid Services (CMS) has launched a redesigned website that is now available to millions of users.

The redesign will guarantee that www.cms.hhs.gov will continue to be one of the agency's most important communication channels. Use of the website has increased from 125.9 million page views in 2003 to 325.7 million page views through November 2005.

The new site is designed to be user-friendly, based on the principle of getting you what you need as efficiently as possible.

CMS worked with consumers, providers and other users to get their advice on upgrading the original site. The redesign has resulted in improved navigation and content organization, current information and an improved Google search feature.

The new website offers one-stop shopping areas targeted to specific needs. For example, providers can browse the site by their areas of interest, then go to the subject area that contains the detailed information.

To ensure frequent users of www.cms.hhs.gov can get what they need from the site, CMS has put more than 400 redirects in place to help them transfer to the new site.

CMS REVIEW OF FEDERAL TAGS FOR LONG TERM CARE FACILITIES

At a recent satellite broadcast, CMS completed a review of the F tags that have been reviewed/revised in the 2004-2005 federal fiscal year, and gave a brief description which tags will be reviewed in 2006. Here is a brief summary of their information:

F314—Pressure Sores	Completed 11/04
F315—Incontinence Care/Catheterization	Completed 6/05
F520—QA & Assurance	Pending
F501—Medical Director	Implemented 11/18/05
F248, 249—Activities	Pending, with a Psychosocial Outcome Guide to be included
F309—Quality of Care	Pending, with guidance on Pain Management; Palliative Care and Hospice to be included
F323, 324—Supervision & Accidents	Pending, to be combined into F323
F329, 330, 331—Unnecessary Drugs	Pending, to be combined in F329
F425, 428, 431—Pharmacy	Pending
F325, 371—Dietary	Pending
F223, 224, 225, 226—Abuse, et al	Pending
F333*—Immunizations	New tag that should be out in June, 2006, to reflect new federal regulation
F698—Past Noncompliance	Deleted. Past noncompliance to be written at appropriate tag and include information on how the facility fixed the problem prior to the state's survey. The facility will not be required to submit a POC.

**The actual draft of this tag came out as F334.*

You may access Appendix PP of the CMS State Operations Manual at the following link:
http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-01

DATE: **October 20, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes:** Citations of Past Noncompliance – Revised Guidance

Letter Summary

The guidance contained in this memorandum:

1) Reinforces the importance of making determinations of current compliance with specific regulatory tags before considering a citation of past noncompliance;
2) Replaces current guidance in the State Operations Manual related to the recommendation of a civil money penalty for a citation of past noncompliance; and
3) Provides instructions for data entry of past noncompliance as users will no longer reference survey data tag number F698 for citations of past noncompliance.

Background

This memorandum clarifies survey and certification actions related to citations of past noncompliance.

The nursing home enforcement regulations provide that the Centers for Medicare & Medicaid Services (CMS) or the state may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.[1] Although citations of past noncompliance account for approximately less than one percent of all nursing home deficiencies cited in 2004, CMS recognizes that the current guidance in the State Operations Manual (SOM) merits further clarification. Attachment 1 clarifies the citation of past noncompliance for nursing homes. This guidance will be incorporated in a future release of the SOM to replace the existing guidance.

[1] 42 CFR 488.430(b)

Discontinued Use of Tag-F698
The use of the generic survey data tag F698 for all past noncompliance citations will be discontinued for all surveys that have a survey exit date beginning on or after November 1, 2005. CMS is proceeding to modify the data system so that the specific nursing home survey data tag (F-tags for health deficiencies or K-tags for life safety code deficiencies) for which there was a finding of past noncompliance may be identified appropriately. Attachment 2 provides technical instructions for documenting past noncompliance at the specific survey data/deficiency tag in the Automated Survey Processing Environment (ASPEN).

The changes incorporated in this final policy and procedure guidance include many of the helpful comments we received from states, CMS regional offices, and interested stakeholders. We appreciate the time and effort reviewers expended to improve upon policies and procedures to assure that our beneficiaries receive quality care in our nation's nursing homes.

Effective Date: The information contained in this memorandum replaces current guidance on past noncompliance in the SOM. This policy is effective for all surveys that have a survey exit date beginning on or after November 1, 2005.

Training: This clarification must be shared with all survey and certification staff, surveyors, their managers, and the state and CMS regional office training coordinators. This information must be shared with nursing home providers in each state.

/s/
Thomas E. Hamilton

Attachments:
Attachment 1 - Determining Citations of Past Noncompliance at the Time of the Current Survey in a Nursing Home
Attachment 2 – Technical Instructions for Entering Nursing Home Citations of Past Noncompliance into ASPEN

cc: Survey and Certification Regional Office Management (G-5)
Jack Williams, Division of National Systems

Attachment 1

Determining Citations of Past Noncompliance at the Time of the Current Survey in a Nursing Home

Past noncompliance may be identified during any survey of a nursing home. Findings of past noncompliance may come to light more frequently during investigations of complaints about the care and services provided to residents in a nursing home.

To cite past noncompliance with a specific survey data tag (F-tag or K-tag), all of the following three criteria must be met:

1) The facility was not in compliance with the specific regulatory requirement(s) (as referenced by the specific F-tag or K-tag) at the time the situation occurred;
2) The noncompliance occurred after the exit date of the last standard recertification survey and before the survey (standard, complaint, or revisit) currently being conducted; and
3) There is sufficient evidence that the facility corrected the noncompliance and is in substantial compliance at the time of the current survey for the specific regulatory requirement(s), as referenced by the specific F-tag or K-tag.

A nursing home does not provide a plan of correction for a deficiency cited as past noncompliance as the deficiency is already corrected; however, the survey team documents the facility's corrective actions on the CMS-2567.

For the purpose of making determinations of current noncompliance or past noncompliance using the current sampled residents, the survey team is expected to follow the investigative protocols and surveyor guidance found in Appendices P and PP and Chapter 5 of the State Operations Manual (SOM).

When noncompliance at a deficiency tag is identified, the surveyor may have identified concerns related to other outcome, process, or structure requirements. The surveyor should investigate the identified requirements before determining whether noncompliance is present at those additional tags. Noncompliance in these additional requirements could be an indication of systemic problems in the delivery of care and services within the facility.

For example: In Appendix PP, if noncompliance is identified at tag F314 (pressure ulcer), guidance is provided that directs the surveyor, if concerns were identified in other outcome, process and/or structure requirements, to investigate those concerns before determining whether noncompliance was present at the additional tags. Examples of additional requirements that may have been identified as areas of concern during the investigation of pressure ulcer care include but are not limited to:

- 42 CFR 483.10(b)(11), F157, Notification of Changes
- 42 CFR 483.15(b)(1), F272, Comprehensive Assessments
- 42 CFR 483.20(k), F279, Comprehensive Care Plans
- 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
- 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
- 42 CFR 483.25, F309, Quality of Care
- 42 CFR 483.30(a), F353, Sufficient Staff

- 42 CFR 483.40(a), F385, Physician Supervision
- 42 CFR 483.75(f), F498, Proficiency of Nurse Aides
- 42 CFR 483.75(i)(2), F501, Medical Director

NOTE: The surveyor is not required to investigate all of the above requirements, but only those in which the surveyor had identified specific concerns.

Similar to verifying correction of current noncompliance on a revisit, surveyors should use a variety of methods to determine whether correction of the past noncompliance occurred and continues. This may include, but is not limited to, the following:

- Interviews with facility staff, such as the administrator, nursing staff, social services staff, medical director, quality assessment and assurance committee members, and/or other facility staff, as indicated, to determine what procedures, systems, structures, and processes have been changed.

- Reviewing through observation, interview and record review, how the facility identified and implemented interventions to address the noncompliance. Examples of interventions may include, but are not limited to:

    - The facility's review, revision, or development of policies and/or procedures to address the areas of concerns;
    - The provision and use of new equipment, as necessary;
    - The provision of staff training required to assure ongoing compliance for the implementation and use of new and/or revised policies, procedures, and/or equipment, especially with new and/or temporary staff;
    - The provision of additional staffing, changes in assignments or deployment of staff, as needed; and
    - The provision of a monitoring mechanism to assure that the changes made are being supervised, evaluated, and reinforced by responsible facility staff.

- Evaluating whether the facility has a functioning quality assessment and assurance committee, whose responsibilities include the identification of quality issues; providing timely response to ascertain the cause; implementing corrective action; implementing monitoring mechanisms in place to assure continued correction and revision of approaches as necessary to eliminate the potential risk of occurrence to other residents and to assure continued compliance.

Enforcement Action Subsequent to the Citation of Past Noncompliance

The nursing home enforcement regulation provides that a civil money penalty (CMP) may be imposed for the number of days of past noncompliance since the last standard survey. If the State Survey Agency (SA) chooses to recommend the imposition of a remedy for a citation of past noncompliance, the only applicable enforcement response is the imposition of a CMP. CMS strongly urges the SAs to recommend the imposition of a CMP for past noncompliance cited at the level of immediate jeopardy.

The SA makes this recommendation to the CMS regional office or the State Medicaid Agency, or both, as determined in accordance with the survey and certification responsibility found in §7300B of the SOM. The Per-Day or Per-Instance CMP may be selected as an enforcement response for past noncompliance. When it is difficult to accurately establish when the past noncompliance occurred, the selection of a Per-Instance CMP would be appropriate. (The procedures related to CMPs may be found at §§7510 through 7536 of the SOM.)

References: Related State Operations Manual Sections

- Chapter 5 – Complaint Procedures (will be revised to incorporate this policy)
- §7300 B – Survey and Certification Responsibility
- §7306C – When State Recommends a Civil Money Penalty for Past Noncompliance
- §§7400 through 7400F3- Enforcement Remedies for Skilled Nursing Facilities and Nursing Facilities
- §§7510 through 7536B – Civil Money Penalties (will be revised to incorporate this policy)
- §§7809 through 7809F – Nurse Aide Training and Competency Evaluation Program and Competency Evaluation Program Disapprovals
- Appendix P – Survey Protocol for Long Term Care Facilities (will be revised to incorporate this policy)
- Appendix PP - Guidance to Surveyors for Long Term Care Facilities

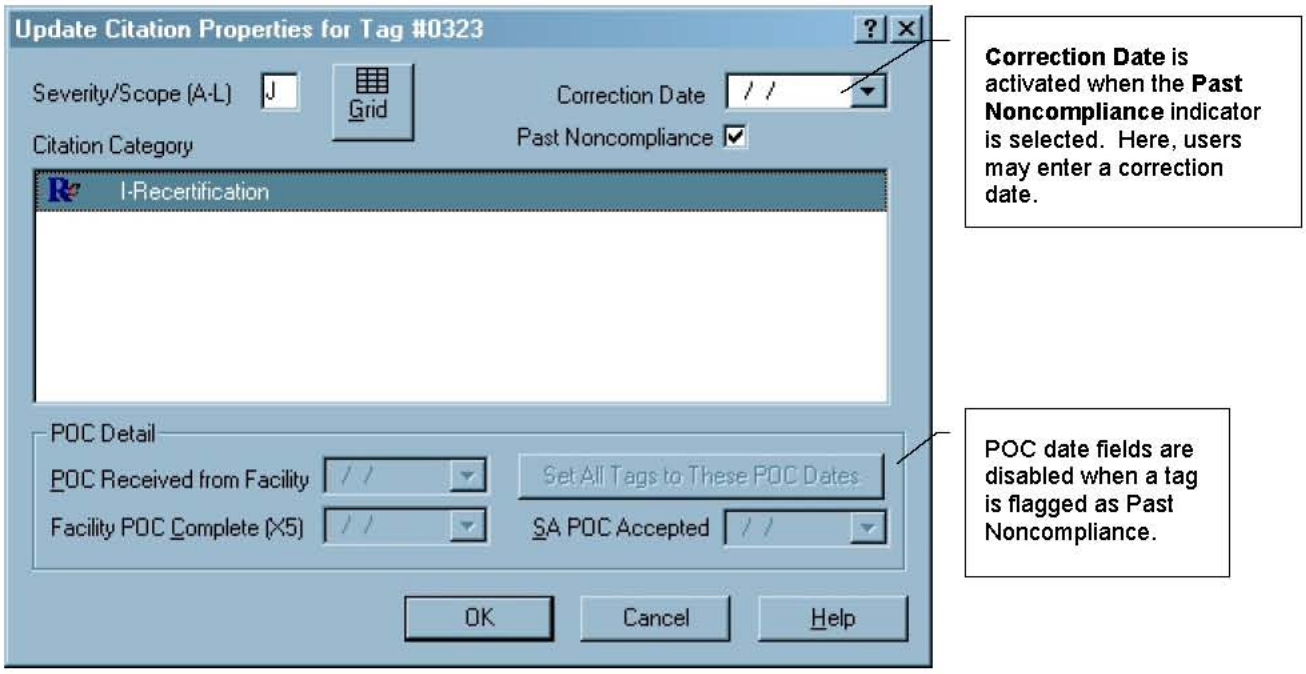
This policy is effective for all surveys that have a survey exit date beginning on or after November 1, 2005.

Technical Instructions for Entering Nursing Home Citations of Past Noncompliance into ASPEN

Past Noncompliance in ASPEN

For nursing home surveys with a survey exit date on or after November 1, 2005, states will no longer use deficiency tag F-698 in ASPEN to cite past noncompliance. Instead, states will indicate the past noncompliance at the actual deficiency tag where past noncompliance was identified.

The Past Noncompliance indicator has been added to Citation Properties in ASPEN (ACO, AST, AEM, ACTS and ASE):



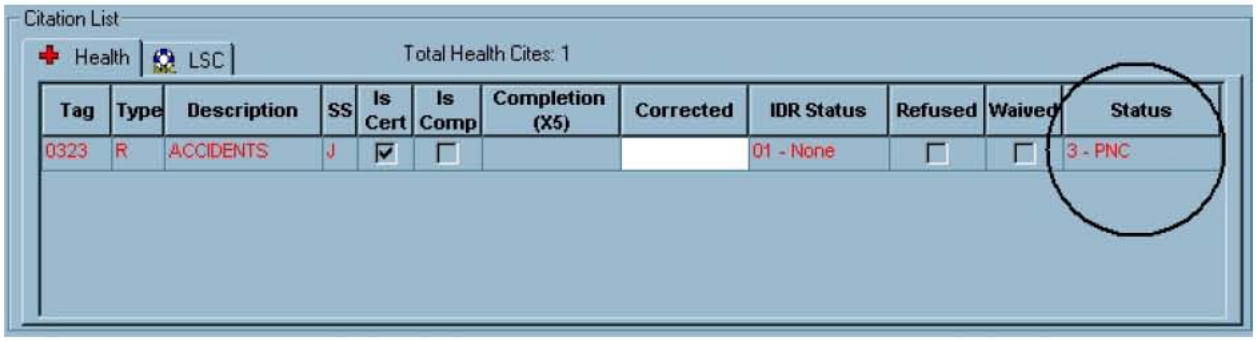
When past noncompliance is selected, a Correction Date field is enabled for the survey data tag. If users enter a correction date, the correction date must be before the survey start date of the visit identifying past noncompliance.

Implementation Details

- Past noncompliance may be cited on Health and Life Safety Code surveys of nursing homes.
- Past noncompliance may be cited on any type of survey (standard recertification, abbreviated standard, e.g., complaint and revisit).
- Data about past noncompliance tags are not carried forward to subsequent revisit surveys.
- ASPEN will ignore past noncompliance citations when users cascade Completion (X5) dates and Correction dates across many citations.
- Tags cited as past noncompliance will not be eligible for "waived" or "refused" status. Tags that are already "waived" or "refused" are prevented from being cited as past noncompliance.
- The citation's POC Detail fields (POC Received from Facility, Facility POC Complete (X5), SA POC Approved, Set All Tags to These POC Dates) are disabled for past noncompliance tags. If a citation has POC Detail dates already entered and is then flagged as past noncompliance, the dates will be removed.
- IDR will be allowed for past noncompliance tags.

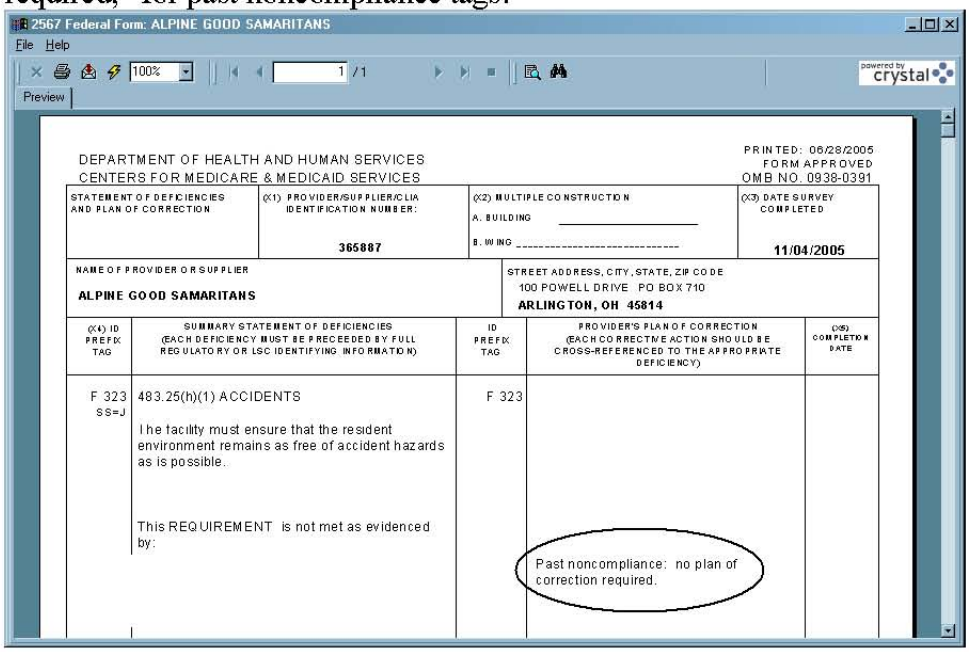
Upload of Past Noncompliance Tags to OSCAR

The certification kit in ASPEN will display past noncompliance tags status as "3 – PNC". Past noncompliance citations will be uploaded to OSCAR with a deficiency status code of 3. If users obtain deficiency data from OSCAR, they should take this into account as they query for reports.



Notation of Past Noncompliance Tags on the CMS-2567

ASPEN will print tags cited as past noncompliance in tag number order on the CMS-2567. The Provider's Plan of Correction column will print "Past noncompliance: no plan of correction required," for past noncompliance tags:



The CMS-2567B will not include tags cited as past noncompliance.

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-02

DATE: **October 20, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **FYI - Release of Brochure Describing the Quality Indicator Survey (QIS) Demonstration Project**

Letter Summary

For your information, we are providing a brochure that provides a brief description of the QIS and the 5-State demonstration and evaluation.

Discussion: Attached to this memorandum is a 4-page brochure describing the QIS and the Centers for Medicare & Medicaid Services Demonstration. The document provides information about the features of the QIS and the 5-State Demonstration in Connecticut, Kansas, Ohio, California, and Louisiana. You may use this brochure at your discretion to provide information on this project to any interested party.

Training: There is no training required concerning this information. This is being distributed for your information.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

CMS Quality Indicator Survey Demonstration Project

Overview of the QIS Process and Demonstration

QIS Survey Overview

The Quality Indicator Survey (QIS) is a revised long-term care survey process that was developed under Centers for Medicare & Medicaid Services (CMS) oversight through a multi-year contract. The QIS was designed as a staged process for use by surveyors to systematically and objectively review all regulatory areas and subsequently focus on selected areas for further review.

The QIS provides a structure for an initial review of larger samples of residents based on the MDS, observations, interviews, and medical record reviews. Utilizing onsite automation, survey findings from the first stage are combined to provide rates on a comprehensive set of Quality of Care Indicators (QCIs) covering all resident- and facility-level federal regulations for nursing homes. The second stage then provides surveyors the opportunity to focus survey resources on further investigation of care areas where concerns exist. Although the survey process has been revised under the QIS, the federal regulations and interpretive guidance remain unchanged.

The QIS was designed to achieve several objectives:

- Improve consistency and accuracy of quality of care and quality of life problem identification using a more structured process;
- Comprehensively review the full range of regulatory care areas within current survey resources;
- Enhance documentation by organizing survey findings through automation; and
- Focus survey resources on facilities with the largest number of quality concerns.

Initial testing of the QIS process has revealed that it yields increased consistency and improved documentation of survey findings. Given the promising results of these tests, CMS now wishes to evaluate the QIS on a larger scale using surveys of record through a demonstration, with an independent evaluation.

QIS Demonstration Overview

For the purposes of the QIS Demonstration, CMS has designated the QIS as a standard survey. Some facilities in Demonstration states will be surveyed using the QIS as the survey of record; however, most facilities in these states will be surveyed using the current survey process, now known as the traditional survey.

The demonstration and evaluation of the QIS will be conducted in five states: California, Connecticut, Kansas, Louisiana, and Ohio. These five states were selected from among twenty-five volunteering states based on several criteria, including: geographic balance; representation of rural areas; citation history; use of technology; and average survey time. One state was selected based on its primarily rural population.

Throughout the Demonstration, the QIS surveys will be observed by contractors whose role will be to evaluate the QIS and make recommendations to continuously improve the QIS process. The evaluation findings will ultimately be used by CMS in determining whether to replace the traditional survey with the QIS on a national scale.

Participating states will be trained on the use of the QIS protocols and software in two phases, the first beginning in September 2005 and second beginning in February 2006. Connecticut, Kansas, and Ohio will participate in the first phase, and California and Louisiana will take part in the second phase. The training approach will be evaluated and refined between the first and second phases.

Training will be comprised of classroom training, training surveys, and surveys of record during which training staff will be present. During the initial QIS surveys in each state, training contractor staff will be present to provide guidance on the use of the QIS protocols. Later on, evaluation contractor staff will accompany some survey teams to evaluate the QIS process.

In summary, the QIS Demonstration has several objectives: determine consistency of QIS when implemented in five states as surveys of record; assess time required to conduct QIS; continuously improve upon QIS process; and test training approaches that may be used for widespread training.

Description of the QIS

The QIS process utilizes customized software, called the "QIS Data Collection Tool" (QIS DCT), to guide surveyors through a structured, two-staged investigation. Figure 1 on the following page provides a step-by-step overview of the QIS process. The process begins with offsite preparation activities (similar to those completed during the traditional federal long-term care survey process), which include preparation of team assignments and review of available information regarding prior deficiencies, complaints, ombudsman information, and existing waivers/variances. Unlike the traditional survey process, the QIS does not require surveyors to review the Quality Measure/Quality Indicator (QM/QI) and OSCAR 4 reports or preselect potential residents for review prior to the survey. MDS data are also requested and loaded offsite into sur-

Continued on page 2

DESCRIPTION OF THE QIS—CONTINUED

veyors' computers and are used to calculate the MDS-based QCIs and create the resident pool from which the Stage I samples are randomly selected.

Following the offsite activities, and upon entry into the facility, a formal entrance conference is held during which necessary information is requested from the facility. Concurrent to the entrance conference, an abbreviated tour of the facility is conducted to provide an orientation to the resident population, staff, and facility layout. Unlike the traditional survey process, the purpose of the tour under the QIS process is not to select a sample of residents for review nor to gather detailed information regarding specific concerns.

Three distinct Stage I samples are selected. These include: 1) the MDS sample (which is drawn offsite); 2) the Census sample; and 3) the Admission sample. The MDS sample includes facility-reported information for all residents who had an MDS assessment at any time within the past six months (except discharge or re-entry assessments). The Census sample includes 40 randomly selected residents in the facility at the time of the onsite visit, and the Admission sample includes 30 recent admissions (emphasizing SNF post-acute patients and long-stay admissions on critical issues such as rehospitalization, death, or functional loss). In addition to these three samples, other residents can be sampled at the surveyors' discretion (referred to as the Surveyor-initiated sample).

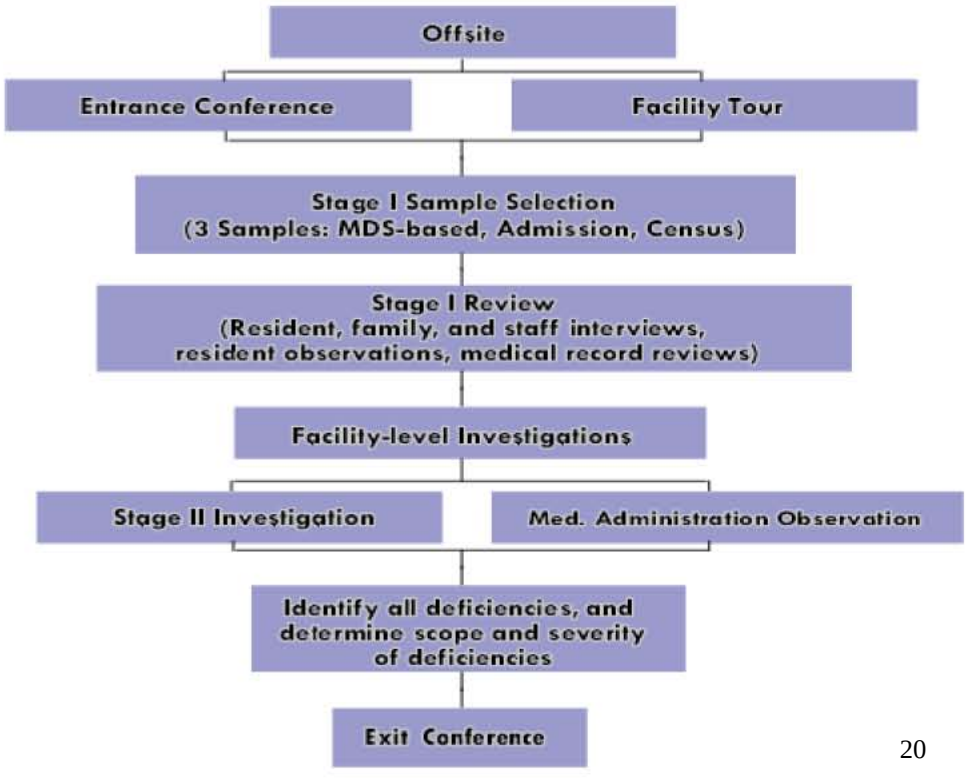
Stage I involves a preliminary investigation of both the Census and Admission samples, covering all regulatory areas. This review is through staff, resident, and family interviews, resident observations, and medical record reviews. Concurrent with the resident-level tasks, facility-level investigations are initiated, which include a Resident Council interview, observations of dining and kitchen, and reviews of the facility's infection control practices, demand billing process, and quality assessment and assurance program. (Additional facility-level investigations, including abuse prohibition, environment, nursing service sufficient staff, resident funds, and admission, transfer, discharge are completed only if triggered during Stage I.) These onsite data are used together with MDS data to construct resident-centered outcome and process indicators, called Quality of Care Indicators (QCIs).

Upon completion of Stage I, the QIS DCT is used to calculate the QCI results, which identify Care Areas that will require further investigation during Stage II. When the rate of a QCI exceeds a specified national benchmark or "threshold," that QCI identifies or "triggers" a Care Area for Stage II investigation. The results of Stage I provide the team with a list of the potential facility and resident care problems and preliminary information on each, but a complete Stage II investigation is required to determine whether deficient practices exist.

Stage II involves a more in-depth resident-level investigation of Care Areas identified at the conclusion of Stage I. Investigations follow a set of investigative protocols that assist the surveyor in completing an organized and systematic review of the triggered Care Areas. The protocols consist of probes that guide the surveyor through the investigation and assist in determining whether the facility is in compliance with the associated regulations (i.e., whether the "critical elements" of care are in place). Once the surveyor completes each investigation and determines whether each of the critical elements was met, all findings are entered into the QIS DCT. For each unmet critical element, the QIS DCT displays possible F tags for citation and requires the surveyor to enter relevant findings and assign an appropriate severity level. Concurrent to the Stage II investigation, medication administration is observed for ten residents selected

Continued on page 3

FIGURE 1: OVERVIEW OF THE QIS PROCESS



DESCRIPTION OF THE QIS—CONTINUED

for review during Stage II. If no Care Areas are triggered during Stage I, certain facility-level investigations must still be completed.

After all facility-level and Stage II resident-level investigations have been completed, the team analyzes the results to determine whether deficient practices exist. An exit conference is then conducted, during which the facility is informed of the survey findings.

DIFFERENCES BETWEEN THE QIS AND TRADITIONAL SURVEY PROCESS

TRADITIONAL SURVEY PROCESS

Information requested of facility upon survey entrance

- Quality Measure/Quality Indicator Report
- Roster Sample Matrix Form (CMS 802)

Tour

Gather information about concerns that have been pre-selected, new concerns, and other candidates for the sample. Determine whether residents pre-selected for the Phase I sample are still present in the facility.

Sample selection

- Residents selected offsite based on facility's QIs of concern. Sample size is determined by facility census.
- Determine whether any pre-selected concerns should be dropped and whether any pre-selected residents should be substituted based on review of Roster/Sample Matrix and findings from the tour.
- Determine which pre-selected Phase I sample residents are interviewable and number of reviews to complete based on census.
- Select residents for review type.

Survey structure

Phase I involves both comprehensive and focused reviews. Phase II involves focused and closed record reviews.

Review process

Surveyors complete the Resident Review, which includes selected investigative protocols for key regulatory tags.

Automation

At this point, most data collection is done on paper; computers are used only for the Statement of Deficiencies.

Group interview

Meeting with the Resident Group or Council (includes review of resident council minutes to identify concerns).

QIS PROCESS

Information requested of facility upon survey entrance

- Alphabetical list of residents and their room numbers.
- List of new admissions and discharges over last 30 days.

Tour

Initial brief review to gain information about the resident population, staff, and facility layout. The purpose is not to select a sample of residents for review nor to gather detailed information regarding specific concerns.

Sample selection

Four samples selected by the QIS DCT, including:

- MDS Offsite sample – residents with an MDS within 180 days prior to survey.
- Random Admission sample – 30 residents admitted more than 30 days prior to survey who had an MDS within 180 days prior to survey.
- Random Census sample – 40 residents currently in facility selected through offsite and onsite activities.
- Surveyor-initiated sample – residents selected at surveyor's discretion.

Survey structure

Stage I involves a preliminary investigation of all regulatory areas in Admission, Census, and Surveyor-initiated samples; Stage II involves further investigation of triggered Care Areas in Stage II sample chosen based on Stage I findings.

Review process

Follow consistent protocols for making observations, conducting interviews, and reviewing charts in Stage I; also includes specific structure for Stage II review and documentation.

Automation

Each team member uses tablet PCs throughout to record findings that are synthesized and organized by computer.

Group interview

Group interview replaced by Resident Council President/ Representative interview, supplemented by individual resident interviews.

HISTORY AND DEVELOPMENT OF THE QIS

The University of Colorado's Division of Health Care Policy and Research and the University of Wisconsin-Madison's Center for Health Systems Research and Analysis developed the QIS with information systems support provided by Maverick Systems, Inc., and Alpine Technologies through a contract from CMS for which RTI International was the prime contractor.

The QIS process, tools, software, and training materials have undergone extensive revisions and refinements over the years through pilot, feasibility, alpha, and beta tests led by teams of researchers, state surveyors, and CMS staff in numerous facilities throughout the country. The QIS Demonstration will enable CMS to further refine and improve upon the QIS process before determining whether to proceed with national implementation.

Under the QIS Demonstration, the University of Colorado will be responsible for providing surveyor training and technical support, with additional technical support provided by subcontractors Alpine Technologies and Iowa Foundation for Medical Care. The demonstration evaluation will be conducted by Abt Associates, Inc., and the UCLA Borun Center for Gerontological Research, with assistance from the University of Colorado. Remtech Services, Inc., is participating in the development of training methods.

During the Demonstration, a CMS team will provide oversight and guidance on all aspects of the QIS Demonstration implementation, evaluation design and performance, and refinements to the QIS process, as well as communication with participating states, their stakeholders, and other interested parties.

Questions regarding the QIS Demonstration Project may be directed to Fred Gladden at 410-786-3033 or FGladden@cms.hhs.gov.

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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-03 (rev)

DATE: **November 17, 2005**

TO: State Survey Agency Directors

FROM: Director

SUBJECT: Nursing Home Immunization Requirement

Letter Summary

A final rule published by the Centers for Medicare & Medicaid Services (CMS) on October 7, 2005 (70 FR 58834) requires Medicare & Medicaid participating nursing homes to provide residents with the opportunity to be immunized against influenza and pneumonia.

An advance copy of the new surveyor guidance for immunization requirements will be published in late spring of 2006.

Background/Facts:
Research has shown that vaccination programs in nursing homes have resulted in positive outcomes for residents. Nursing homes that have high rates of vaccinated residents have demonstrated not only fewer outbreaks of influenza than homes with lower vaccination rates but a significant decrease in the rate of hospitalization, pneumonia, and related mortalities as well. As part of CMS' continued commitment to enhance assessment of health status and delivery of preventive services to our beneficiaries, we collaborated with the Centers for Disease Control and Prevention to improve influenza and pneumococcal immunization coverage.

Discussion:
A final rule published by CMS on October 7, 2005 (70 FR 58834) requires Medicare & Medicaid participating nursing homes to provide residents with the opportunity to be immunized against influenza and pneumonia. The new regulation, which will be codified as 42 CFR 483.25(n) "Quality of Care," complements the existing federal requirement at 42 CFR §483.65(a), "Infection Control," that requires facilities to have an infection control program that is effective for investigating, controlling, and preventing infections.

The new regulation requires facilities to develop and implement specific policies and procedures for the provision of influenza and pneumococcal immunizations. In addition, the facility must ensure that:

- Residents or their legal representatives receive education regarding the benefits and potential side effects of the immunizations before they are offered the immunizations;

- As appropriate, residents will be offered the opportunity to receive the immunizations annually (1 Oct-30 Mar) for influenza;

- As appropriate, residents will be offered the opportunity to receive a one time dose of vaccine for pneumococcal pneumonia after the age of 65;

- Residents or their legal representatives have the right to refuse the immunizations; and

- The facility must provide documentation of the provision of education and the receipt, contraindication, and/or refusal for the immunizations in the resident's medical record.

CMS is developing survey guidance including interpretive guidelines and severity guidance for this new regulation. An advance copy of the guidance is expected to be released in the late spring of 2006 in a survey and certification memorandum that will also include an educational tool to be used for the implementation of the new rule. Additionally, in June 2006, CMS' Office of Clinical Standards and Quality will release a new immunization quality measure that will be incorporated into the survey guidance for this requirement.

In the interval prior to the release of the new guidance, surveyors should continue to survey for immunization according to the current survey process. Interpretive guidance for infection control concerns may be found at tag F-441 (42 CFR §483.65(a)). If the nursing home demonstrates it could not immunize residents due to a shortage or delay in vaccine availability, a deficiency is not to be cited. Surveyors should provide information regarding the new regulation to providers, including the need to develop the appropriate policies and procedures.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: This clarification should be shared with all RO survey and certification staff, State agency surveyors, managers, and the RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-05

DATE: **November 14, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Nursing Home Medical Director Tag and Accompanying Training Materials

Letter Summary

- We appreciate the training that States have provided for the revised F501 Nursing Home Medical Director tag that becomes effective November 18, 2005.
- We have developed F501 Medical Director Training materials and they are ready for use for surveyors who have not already been trained.
- A copy of the Final Version of the F501guidance is attached.

The revised tag F501, Medical Director (for nursing homes) will be effective on November 18, 2005. Training materials are now available for use in training all nursing home surveyors who have not already received instruction on this revised tag. The training materials are attached and include the following:

- Tag F501 Guidance – Final Version (Word file)
- PowerPoint presentation (Powerpoint file)
- Instructor's Notes - (PDF file)

We expect that the enclosed training materials will be used to train all nursing home surveyors who have not received tag F501 training. We encourage training to be conducted in person with group discussion to optimize learning. However, if this is not feasible to meet the needs of your surveyors, it is acceptable to use other methods. These training materials may also be used to communicate with provider groups and other stakeholders.

To facilitate training, a national teleconference occurred on November 8, 2005 which offered an opportunity for Regional Training Administrators (RTAs), State Training Coordinators (STCs), and surveyors to receive Medical Director training.

RTAs and STCs will document the completion of training on tag F501 to facilitate later entry of the information into the Learning Management System.

The final guidance for tag F501 will be available on the Transmittals web page at www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp.

For questions on this memorandum, please contact Linda O'Hara at 410-786-8347 or via email at linda.ohara@cms.hhs.gov.

Effective Date: This revised tag F501 is effective November 18, 2005. Please ensure that all staff are apprised of this information as soon as possible.

Training: This information should be shared with all appropriate survey and certification staff, surveyors and their managers.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Enclosures: Tag F501 – Final Version (Word file);
PowerPoint presentation (Powerpoint file);
Instructor's Notes - (PDF file).

INTENT: *(F501) 483.75(i) Medical Director*

The intent of this requirement is that:

- *The facility has a licensed physician who serves as the medical director to coordinate medical care in the facility and provide clinical guidance and oversight regarding the implementation of resident care policies;*

- *The medical director collaborates with the facility leadership, staff, and other practitioners and consultants to help develop, implement and evaluate resident care policies and procedures that reflect current standards of practice; and*

- *The medical director helps the facility identify, evaluate, and address/resolve medical and clinical concerns and issues that:*

    - *Affect resident care, medical care or quality of life; or*

    - *Are related to the provision of services by physicians and other licensed health care practitioners.*

NOTE: *While many medical directors also serve as attending physicians, the roles and functions of a medical director are separate from those of an attending physician. The medical director's role involves the coordination of facility-wide medical care while the attending physician's role involves primary responsibility for the medical care of individual residents.*[1]

DEFINITIONS

Definitions are provided to clarify terms related to the provision of medical director services.

- *"Attending Physician" refers to the physician who has the primary responsibility for the medical care of a resident.*

- *"Current standards of practice" refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.*

- *"Medical care" refers to the practice of medicine as consistent with State laws and regulations.*

- *"Medical director" refers to a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under*

these regulations, the medical director is responsible for coordinating medical care and helping to develop, implement and evaluate resident care policies and procedures that reflect current standards of practice.

- *"Resident care policies and procedures" – Resident care policies are the facility's overall goals, directives, and governing Statements that direct the delivery of care and services to residents. Resident care procedures describe the processes by which the facility provides care to residents that is consistent with current standards of practice and facility policies.*

OVERVIEW

The medical director has an important leadership role in actively helping long term care facilities provide quality care. The regulation requires each facility to have a medical director who is responsible for the implementation of resident care policies and the coordination of medical care. These two roles provide the basis for the functions and tasks discussed in this guidance. The medical director's roles and functions require the physician serving in that capacity to be knowledgeable about current standards of practice in caring for long term care residents, and about how to coordinate and oversee related practitioners. As a clinician, the medical director plays a pivotal role in providing clinical leadership regarding application of current standards of practice for resident care and new or proposed treatments, practices, and approaches to care. The medical director's input promotes the attainment of optimal resident outcomes which may also be influenced by many other factors, such as resident characteristics and preferences, individual attending physician actions, and facility support. The 2001 Institute of Medicine report, "Improving the Quality of Long Term Care," urged facilities to give medical directors greater authority for medical services and care. The report states, "nursing homes should develop structures and processes that enable and require a more focused and dedicated medical staff responsible for patient care."[2]

The medical director is in a position, because of his/her roles and functions, to provide input to surveyors on physician issues, individual resident's clinical issues, and the facility's clinical practices. The text "Medical Direction in Long Term-Care"[3] asserts that:

> *"The Medical Director has an important role in helping the facility deal with regulatory and survey issues... the medical director can help ensure that appropriate systems exist to facilitate good medical care, establish and apply good monitoring systems and effective documentation and follow up of findings, and help improve physician compliance with regulations, including required visits. During and after the survey process, the medical director can clarify for the surveyors clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the*

nature and scope of the facility's deficiencies, and help the facility draft corrective actions."

Nationally accepted statements concerning the roles, responsibilities and functions of a medical director can be found at the American Medical Directors Association website at www.amda.com.

NOTE: *References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

MEDICAL DIRECTION

The facility is responsible for designating a medical director, who is currently licensed as a physician in the State(s) in which the facility(ies) he/she serves is (are) located. The facility may provide for this service through any of several methods, such as direct employment, contractual arrangements, or another type of agreement. Whatever the arrangement or method employed, the facility and the medical director should identify the expectations for how the medical director will work with the facility to effectively implement resident care policies and coordinate medical care.

NOTE: *While the roles of medical directors who work for multi-facility organizations with corporate or regional offices may vary for policy development, the medical directors, nonetheless, should be involved in facility level issues such as application of those policies to the care of the facility's residents.*

Implementation of Resident Care Policies and Procedures

The facility is responsible for obtaining the medical director's ongoing guidance in the development and implementation of resident care policies, including review and revision of existing policies. The medical director role involves collaborating with the facility regarding the policies and protocols that guide clinical decision making (for example, interpretation of clinical information, treatment selection, and monitoring of risks and benefits of interventions) by any of the following: facility staff; licensed physicians; nurse practitioners; physician assistants; clinical nurse specialists; licensed, certified, or registered health care professionals such as nurses, therapists, dieticians, pharmacists, social workers, and other health care workers.

The medical director has a key role in helping the facility to incorporate current standards of practice into resident care policies and procedures/guidelines to help assure that they address the needs of the residents. Although regulations do not require the medical director to sign the policies or procedures, the facility should be able to show

that its development, review, and approval of resident care policies included the medical director's input.

This requirement does not imply that the medical director must carry out the policies and procedures or supervise staff performance directly, but rather must guide, approve, and help oversee the implementation of the policies and procedures. Examples of resident care policies include, but are not limited to:

- *Admission policies and care practices that address the types of residents that may be admitted and retained based upon the ability of the facility to provide the services and care to meet their needs;*

- *The integrated delivery of care and services, such as medical, nursing, pharmacy, social, rehabilitative and dietary services, which includes clinical assessments, analysis of assessment findings, care planning including preventive care, care plan monitoring and modification, infection control (including isolation or special care), transfers to other settings, and discharge planning;*

- *The use and availability of ancillary services such as x-ray and laboratory;*

- *The availability, qualifications, and clinical functions of staff necessary to meet resident care needs;*

- *Resident formulation and facility implementation of advance directives (in accordance with State law) and end-of-life care;*

- *Provisions that enhance resident decision making, including choice regarding medical care options;*

- *Mechanisms for communicating and resolving issues related to medical care;*

- *Conduct of research, if allowed, within the facility;*

- *Provision of physician services, including (but not limited to):*

    - *Availability of physician services 24 hours a day in case of emergency;*

    - *Review of the resident's overall condition and program of care at each visit, including medications and treatments;*

    - *Documentation of progress notes with signatures;*

    - *Frequency of visits, as required;*

    - *Signing and dating all orders, such as medications, admission orders, and re-admission orders; and*

- *Review of and response to consultant recommendations.*

- *Systems to ensure that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law; and*

- *Procedures and general clinical guidance for facility staff regarding when to contact a practitioner, including information that should be gathered prior to contacting the practitioner regarding a clinical issue/question or change in condition.*

Coordination of Medical Care

The medical director is responsible for the coordination of medical care in the facility. The coordination of medical care means that the medical director helps the facility obtain and maintain timely and appropriate medical care that supports the healthcare needs of the residents, is consistent with current standards of practice, and helps the facility meet its regulatory requirements. In light of the extensive medical needs of the long term care population, physicians have an important role both in providing direct care and in influencing care quality. The medical director helps coordinate and evaluate the medical care within the facility by reviewing and evaluating aspects of physician care and practitioner services, and helping the facility identify, evaluate, and address health care issues related to the quality of care and quality of life of residents. "A medical director should establish a framework for physician participation, and physicians should believe that they are accountable for their actions and their care."[4]

The medical director addresses issues related to the coordination of medical care identified through the facility's quality assessment and assurance committee and quality assurance program, and other activities related to the coordination of care. This includes, but is not limited to, helping the facility:

- *Ensure that residents have primary attending and backup physician coverage;*

- *Ensure that physician and health care practitioner services are available to help residents attain and maintain their highest practicable level of functioning, consistent with regulatory requirements;*

- *Develop a process to review basic physician and health care practitioner credentials (e.g., licensure and pertinent background);*

- *Address and resolve concerns and issues between the physicians, health care practitioners and facility staff; and*

- *Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings.*

Throughout this guidance, a response from a physician implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician agrees that those are medically valid and indicated.

In addition, other areas for medical director input to the facility may include:

- *Facilitating feedback to physicians and other health care practitioners about their performance and practices;*
- *Reviewing individual resident cases as requested or as indicated;*
- *Reviewing consultant recommendations;*
- *Discussing and intervening (as appropriate) with a health care practitioner about medical care that is inconsistent with applicable current standards of care;*
- *Assuring that a system exists to monitor the performance of the health care practitioners;*
- *Guiding physicians regarding specific performance expectations;*
- *Identifying facility or practitioner educational and informational needs;*
- *Providing information to the facility practitioners from sources such as nationally recognized medical care societies and organizations where current clinical information can be obtained; and*
- *Helping educate and provide information to staff, practitioners, residents, families and others.*

NOTE: *This does not imply that the medical director must personally present educational programs.*

REFERENCES

[1] *Pattee JJ, Otteson OJ. (1991). Medical direction in the nursing home (p.5). Minneapolis, MN: Northridge Press.*

[2] *Institute of Medicine (2001). Improving The Quality Of Long-Term Care (pp. 201). Washington, DC: National Academy Press.*

[3] *Levenson, S. A. (1993). Medical Direction In Long-Term Care. A Guidebook For The Future (2nd ed., pp. 135). Durham, NC: Carolina Academic Press.*

[4] *Levenson, SA. Medical Director and Attending Physicians Policy and Procedure Manual for Long-term Care. Dayton, Ohio: MedPass. 2005.*

INVESTIGATIVE PROTOCOL

MEDICAL DIRECTOR

Objective

- *To determine whether the facility has designated a licensed physician to serve as medical director; and*

- *To determine whether the medical director, in collaboration with the facility, coordinates medical care and the implementation of resident care policies.*

Use

Use this protocol for all initial and extended surveys or, as indicated, during any other type of survey. Use this protocol if the survey team has identified:

- *That the facility does not have a licensed physician serving as medical director; and/or*

- *That the facility has designated a licensed physician to serve as medical director; however, concerns or noncompliance identified indicate that:*

    - *The facility has failed to involve the medical director in his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies; and/or*

    - *The medical director may not have performed his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies.*

Procedures

The investigation involves interviews, review of pertinent policies and procedures, and may involve additional review of resident care.

Provision of a Medical Director

Determine whether the medical director is available during the survey to respond to surveyor questions about resident care policies, medical care, and physician issues.

Interview the facility leadership (e.g., Administrator, Director of Nursing [DON], others as appropriate) about how it has identified and reviewed with the medical director his/her roles and functions as a medical director, including those related to coordination of medical care and the facility's clinical practices and care.

Interview the medical director about his/her understanding and performance of the medical director roles and functions, and about the extent of facility support for performing his/her roles and functions.

If the survey team has identified that the facility lacks a medical director, collect information from the facility administrator to:

- *Determine the duration and possible reasons for this problem; and*
- *Identify what the facility has been doing to try to retain a medical director.*

Facility/Medical Director Responsibility for Resident Care Policies

After identifying actual or potential noncompliance with the provision of resident care or medical care:

- *Review related policies/procedures;*
- *Interview facility leadership (e.g., Administrator, DON) to determine how or if they involved the medical director in developing, reviewing, and implementing policies and procedures regarding clinical care of residents (especially where these involve medical and clinical issues; for example, management of causes of delirium, falling, and weight loss) to ensure that they are clinically valid and consistent with current standards of care;*
- *Interview the medical director regarding his/her input into:*
    - *Scope of services the facility has chosen to provide;*
    - *The facility's capacity to care for its residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids, dementia and/or related conditions, or problematic behaviors or complex mood disorders;*
    - *The following areas of concern:*
        - *Appropriateness of care as it relates to clinical services (for example, following orders correctly, communicating important information to physicians in a timely fashion, etc.);*
        - *Processes for accurate assessment, care planning, treatment implementation, and monitoring of care and services to meet resident needs; and*
        - *The review and update of policies and procedures to reflect current standards of practice for resident care (e.g., pressure ulcer*

prevention and treatment and management of: incontinence, pain, fall risk, restraint reduction, and hydration risks) and quality of life.

Coordination of Medical Care/Physician Leadership

If the survey team has identified issues or concerns related to the provision of medical care:

- *Interview appropriate facility staff and management as well as the medical director to determine what happens when a physician (or other healthcare practitioner) has a pattern of inadequate or inappropriate performance or acts contrary to established rules and procedures of the facility; for example, repeatedly late in making visits, fails to take time to discuss resident problems with staff, does not adequately address or document key medical issues when making resident visits, etc;*

- *If concerns are identified for any of the following physician services, determine how the facility obtained the medical director's input in evaluating and coordinating the provision of medical care:*

    - *Assuring that provisions are in place for physician services 24 hours a day and in case of emergency (§483.40(b));*

    - *Assuring that physicians visit residents, provide medical orders, and review a resident's medical condition as required (§483.40(b)&(c));*

    - *Assuring that other practitioners who may perform physician delegated tasks, act within the regulatory requirements and within their scope of practice as defined by State law (§483.40(e)&(f));*

    - *Clarifying that staff know when to contact the medical director; for example, if an attending or covering physician fails to respond to a facility's request to evaluate or discuss a resident with an acute change of condition;*

    - *Clarifying how the medical director is expected to respond when informed that the staff is having difficulty obtaining needed consultations or other medical services; or*

    - *Addressing other concerns between the attending physician and the facility, such as issues identified on medication regimen review, or the problematic use of restraints.*

In addition, determine how the facility and medical director assure that physicians are informed of expectations and facility policies, and how the medical director reviews the

medical care and provides guidance and feedback regarding practitioner performance, as necessary.

Regardless of whether the medical director is the physician member of the quality assurance committee, determine how the facility and medical director exchange information regarding the quality of resident care, medical care, and how the facility disseminates information from the committee to the medical director and attending physicians regarding clinical aspects of care and quality such as infection control, medication and pharmacy issues, incidents and accidents, and other emergency medical issues (§483.75(o)).

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F501)

This requirement has 3 aspects: Having a physician to serve as medical director, implementing resident care policies, and coordinating medical care. As with all other long term care requirements, the citation of a deficiency at F501, Medical Director, is a deficiency regarding the facility's failure to comply with this regulation. The facility is responsible for designating a physician to serve as medical director and is responsible for oversight of, and collaboration with, the medical director to implement resident care policies and to coordinate medical care.

Criteria for Compliance

The facility is in compliance if:

- *They have designated a medical director who is a licensed physician; and*
- *The physician is performing the functions of the position; and*
- *The medical director provides input and helps the facility develop, review and implement resident care policies, based on current clinical standards; and*
- *The medical director assists the facility in the coordination of medical care and services in the facility.*

If not, cite F501.

Noncompliance for F501

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. The survey team must identify whether the noncompliance cited at other tags relates to the medical director's roles and responsibilities. In order to cite at F501 when noncompliance has been identified at another tag, the team must demonstrate an association between the identified deficiency

*and a failure of medical direction. Noncompliance for F501 may include (but is not limited to) the **facility** failure to:*

- *Designate a licensed physician to serve as medical director; or*
- *Obtain the medical director's input for timely and ongoing development, review and approval of resident care policies;*

*Noncompliance for F501 may also include (but is not limited to) the **facility** and **medical director** failure to:*

- *Coordinate and evaluate the medical care within the facility, including the review and evaluation of aspects of physician care and practitioner services;*
- *Identify, evaluate, and address health care issues related to the quality of care and quality of life of residents;*
- *Assure that residents have primary attending and backup physician coverage;*
- *Assure that physician and health care practitioner services reflect current standards of care and are consistent with regulatory requirements;*
- *Address and resolve concerns and issues between the physicians, health care practitioners and facility staff;*
- *Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings;*
- *Review individual resident cases, as warranted, to evaluate quality of care or quality of life concerns or other problematic situations and take appropriate steps to resolve the situation as necessary and as requested;*
- *Review, consider and/or act upon consultant recommendations that affect the facility's resident care policies and procedures or the care of an individual resident, when appropriate;*
- *Discuss and intervene (as appropriate) with the health care practitioner about medical care that is inconsistent with applicable current standards of care; or*
- *Assure that a system exists to monitor the performance and practices of the health care practitioners.*

This does not presume that a facility's noncompliance with the requirements for the delivery of care necessarily reflects on the performance of the medical director.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F501 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of resident care policies and/or medical care.

Deficient practices related to actual or potential harm/negative outcome for F501 may include but are not limited to:

- *Lack of medical director involvement in the development, review and/or implementation of resident care policies that address the types of residents receiving care and services, such as a resident with end-stage renal disease, pressure ulcers, dementia, or that address practices such as restraint use;*

- *Lack of medical director involvement in coordinating medical care regarding problems with physician coverage or availability; or*

- *Lack of medical director response when the facility requests intervention with an attending physician regarding medical care of a resident.*

2. Degree of harm (actual or potential) related to the noncompliance.

Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*

- *If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for F501. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety exists by evaluating the deficient

practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to resident health or safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- *Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and*

- *Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the immediate jeopardy.*

In order to cite immediate jeopardy at this tag, the surveyor must be able to identify the relationship between noncompliance cited as immediate jeopardy at other regulatory tags and the failure of the medical care and systems associated with the roles and responsibilities of the medical director. ***In order to select severity level 4 at F501, both of the following must be present:***

1. *Findings of noncompliance at Severity Level 4 at another tag:*

   - *Must have allowed, caused or resulted in, or is likely to allow, cause or result in serious injury, harm, impairment or death and require immediate correction. The findings of noncompliance associated with immediate jeopardy are written at tags that also show evidence of process failures with respect to the medical director's responsibilities; and*

2. *There is no medical director or the facility failed to involve the medical director in resident care policies or resident care or medical care as appropriate or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:*

   - *To get involved or to intercede with the attending physician in order to facilitate and/or coordinate medical care; and/or*

   - *To provide guidance and/or oversight for relevant resident care policies.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

In order to cite actual harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and failure of medical care or processes and practices associated with roles and responsibilities of the medical director, such as:

1. *Findings of noncompliance at Severity Level 3 at another tag must have caused actual harm:*

    - *The findings of noncompliance associated with actual harm are written at tags that show evidence of process failures with respect to the medical director's responsibilities; and*

2. *There is no medical director or the facility failed to involve the medical director in resident care policies or resident care or medical care as appropriate or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:*

    - *To get involved or intercede with the attending physician in order to facilitate and/or coordinate medical care (medical care and systems associated with roles and responsibilities of the medical director show evidence of breakdown); or*

    - *To provide guidance and/or oversight for resident care policies.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is not Immediate Jeopardy

In order to cite no actual harm with potential for more than minimal harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and the failure of medical care, processes and practices associated with roles and responsibilities of the medical director, such as:

1. *Findings of noncompliance at Severity Level 2 at another tag:*

    - *Must have caused no actual harm with potential for more than minimal harm (Level 2). Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided; and*

2. *There is no medical director or the facility failed to involve the medical director in resident care policies or resident care as appropriate or the medical director had knowledge of an issue with care or physician services, and failed:*

    - *To get involved with or intercede with attending physicians in order to facilitate and/or coordinate medical care; or*

    - *To provide guidance and/or oversight for resident care policies.*

Severity Level 1 Considerations: No actual harm with potential for minimal harm

In order to cite no actual harm with potential for minimal harm at this tag, the survey team must have identified that:

- *There is no medical director; and*

    - *There are no negative resident outcomes that are the result of deficient practice; and*

    - *Medical care and systems associated with roles and responsibilities of the medical director are in place; and*

    - *There has been a relatively short duration of time without a medical director; and*

    - *The facility is actively seeking a new medical director.*

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-06

DATE: **November 14, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: The Use of Foreign Acquired Drugs in Long-Term Care Facilities

Letter Summary

When a long-term care facility is found acquiring and dispensing foreign drugs to residents, the surveyor must assess whether the facility is compliant with 42 C.F.R. § 483.60(a) which states: "a facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."

The purpose of this memorandum is to instruct surveyors on what to do when long-term care (LTC) facilities are acquiring and dispensing of foreign drugs for the purpose of consumption by residents.

The regulations at 42 C.F.R. Part 483 subpart B require LTC facilities to ensure the accurate acquiring, receiving, dispensing and administering of all drugs and biologicals. See section 484.60(a) of the State Operations Manual for further information on the factors that the state survey agency and the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) should consider when determining compliance with this regulation.

Background

The United States (U.S.) Department of Health and Human Services (HHS) is very concerned about the safety risks associated with the unauthorized importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U. S. approved prescription drugs have been of unknown quality. These drugs may be sub-potent, super-potent, expired, contaminated, or ineffective. Since they have been manufactured and/or held outside of our regulatory system, HHS cannot provide adequate assurance to the American public that the drug products delivered to consumers in the U. S. from foreign countries are safe and effective for their intended uses. These concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the U. S.

Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

Importing prescription drugs into the U. S. may violate the FFDCA in one of two ways. First, many drugs imported into the U. S. from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the U. S. that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

The United States Food and Drug Administration (FDA) approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 C.F.R. § 314.50). Generally, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved (21 U.S.C. § 355). The foreign version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the U.S. a prescription drug that was originally manufactured in the U. S. and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the U. S. in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any LTC facility that imports prescription drugs into the U.S. must ensure, among other things, that it imports only FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 C.F.R. § 314.50). The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Determining Compliance

When a facility is found acquiring and dispensing, or allowing the dispensing of foreign drugs/medication to residents in LTC facilities, the surveyors must assess whether the facility is compliant with 42 C.F.R. 483.60(a) which states: "a facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."

We acknowledge that identifying the legal status of drugs dispensed in an LTC facility can be complicated. Indeed, many legal, FDA-approved prescription drugs are manufactured abroad and legally imported into the U. S. for distribution to pharmacies, health care facilities, and other retail outlets. It therefore would be incorrect to conclude that every prescription drug imported into the U. S. from abroad is imported in violation of the FFDCA. Please note, however, that legal FDA-approved prescription drugs imported into the U. S. are generally so imported by the company that manufactured them or by licensed wholesale distributors who work closely with those companies.

If a surveyor becomes aware that an LTC facility is *directly* importing its drugs from foreign countries, that may be a signal that the LTC facility is acquiring those drugs in violation of the FFDCA. If the facility is aware of imported drugs that are not FDA-approved the surveyor should cite the facility for unsafe practice under §483.60(a) pharmacy services and report the finding to the FDA.

When a surveyor finds that an individual residing in a nursing home has in his/her possession imported prescription drugs that are not FDA-approved, the surveyor should ascertain whether the facility is aware of the illegal drug:

- If the facility states that they are unaware of the imported drugs the surveyor should then ascertain whether the drugs are delivered to the resident via the facility staff or are self-administered.

    - If the drugs are administered by facility staff, the surveyor should cite the facility for the unsafe practice under §483.60(a) pharmacy services and report the finding to the FDA.

    - If the resident it self-administering the drugs without the facility's knowledge the surveyor should notify the facility of the unsafe practice.

In addition, virtually all of the prescription drugs imported into the U.S. by individual consumers violate the FFDCA because they are dispensed by foreign pharmacies that stock foreign versions of FDA-approved drugs that lack FDA-approval and/or proper labeling, or because they were originally manufactured in the U.S., sent abroad, and then imported by a person other than the manufacturer in violation of 21 U.S.C. § 381(d)(1). Accordingly, evidence of personal importation is almost certainly an indication that the imported prescription drugs have been obtained in violation of federal law.

In the event that a violative activity is identified, we recommend that, in addition to assessing compliance with 42 C.F.R. 483.60(a), you report the findings to the FDA, which is the agency within HHS that is responsible for enforcing the FFDCA.

The FDA point of contact is:

Ada Irizarry
CDER Office of Compliance
Division of New Drugs and Labeling Compliance
11919 Rockville Pike, Room 348
Rockville, MD 20852
(301) 827-8967 or www.fda.gov

For questions on this memorandum, please contact Debra Swinton-Spears at (410)-786-7506 or e-mail at debra.swinton-spears@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: The information contained in this announcement should be shared with all nursing home surveyors and supervisors.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

To: ICF-MR Providers

From: Steve Corya, Medical Surveyor Supervisor; South Region
Chris Greeney, Medical Surveyor Supervisor; North Region

CC: Kim Rhoades, ISDH Survey Manager
Rick Powers, ISDH Life Safety Code Surveyor Supervisor

Date: 12/22/2005

Re: CMS Clarification on Frequency of Evacuation Drills

Attached you will find recent correspondence sent from the Center for Medicaid/Medicare Services (CMS) region 5 office detailing how often an ICF-MR must conduct evacuation drills. The region 5 office indicated the correspondence originated with the CMS Central Office in Baltimore. In summary the article defines "quarters" used in the regulation at W440, as any consecutive three-month period in a year. An evacuation drill would be expected once per shift, per quarter, as defined. For example, if a facility conducts a first shift evacuation drill in February, February becomes the first month of the quarter. Another first shift evacuation drill would have to be conducted by the end of May in order to remain in compliance.

It should be noted this correspondence uses different types of evacuation drills (instead of solely fire evacuation drills) in the CMS provided sample drill schedule. Rick Powers, Life Safety Code Surveyor Supervisor, indicated Life Safety Code requirements still expect there to be 12 fire evacuation drills in a 12-month period. While ICF-MR surveyors will focus on evaluating compliance with W440 by reviewing for at least one evacuation drill (any type) per shift per quarter, providers need to ensure Life Safety Code requirements for fire evacuations continue to be met.

Feel free to contact the Medical Surveyor Supervisor of your region if you have any questions.

Q2. How often must an ICF/MR conduct evacuation drills?

A2. While the regulation at W440 (42 CFR §483.470(i)(1)) states that evacuation drills must be conducted for each shift of staff at least "quarterly," the interpretive guidelines for W440 say "at least once in a 3-month period." Neither the regulation at W440 (42 CFR §483.470(i)(1)) nor its guidelines clarify this time span any further. They do not require that drills be conducted within a 90-day period. They do not require that drills be conducted during calendar quarters (January–March, April–June, July–September, October–December) or static quarters (same every year, every shift, every place). Because quarters are considered to be 3 consecutive months, the 3-month period referred to in W440 is considered to be 3 consecutive months. The month in which the first drill is completed establishes the beginning of the first quarter.

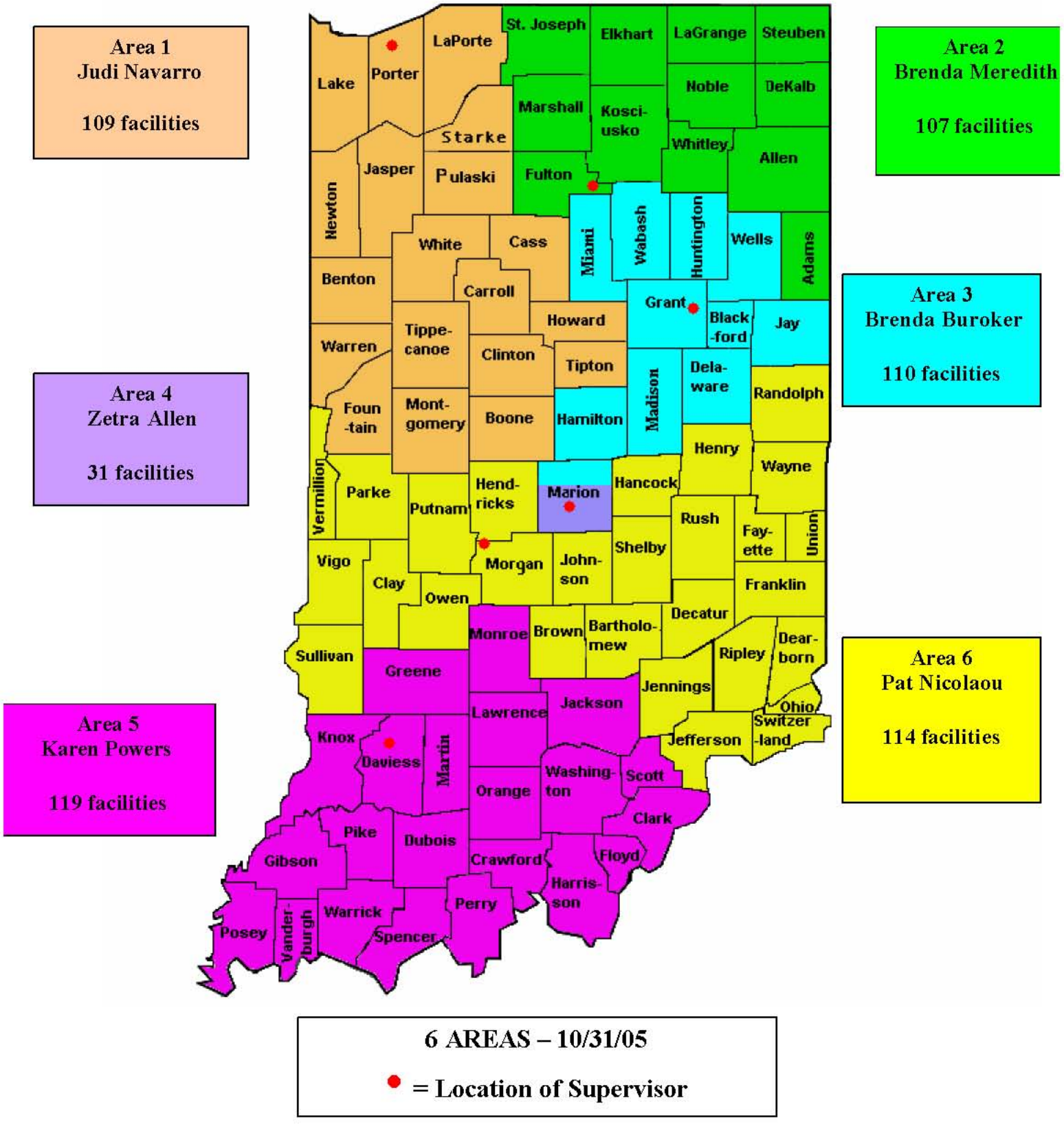
Therefore, the facility must conduct an evacuation drill during each shift of staff at least once within any consecutive 3-month period of the 12-month period. *Put another way, a surveyor would expect to see no more than 3 consecutive months elapse between any evacuation drill on each shift.* Therefore, as in the sample drill schedule below, if a facility held a drill for the first shift on February 3, a second drill would be expected at any time within the third consecutive month following February, or by the end of May. In other words, to be in compliance with W440, it would not be necessary for the next drill for that shift to be completed by May 3 as long as the drill is completed by May 31.

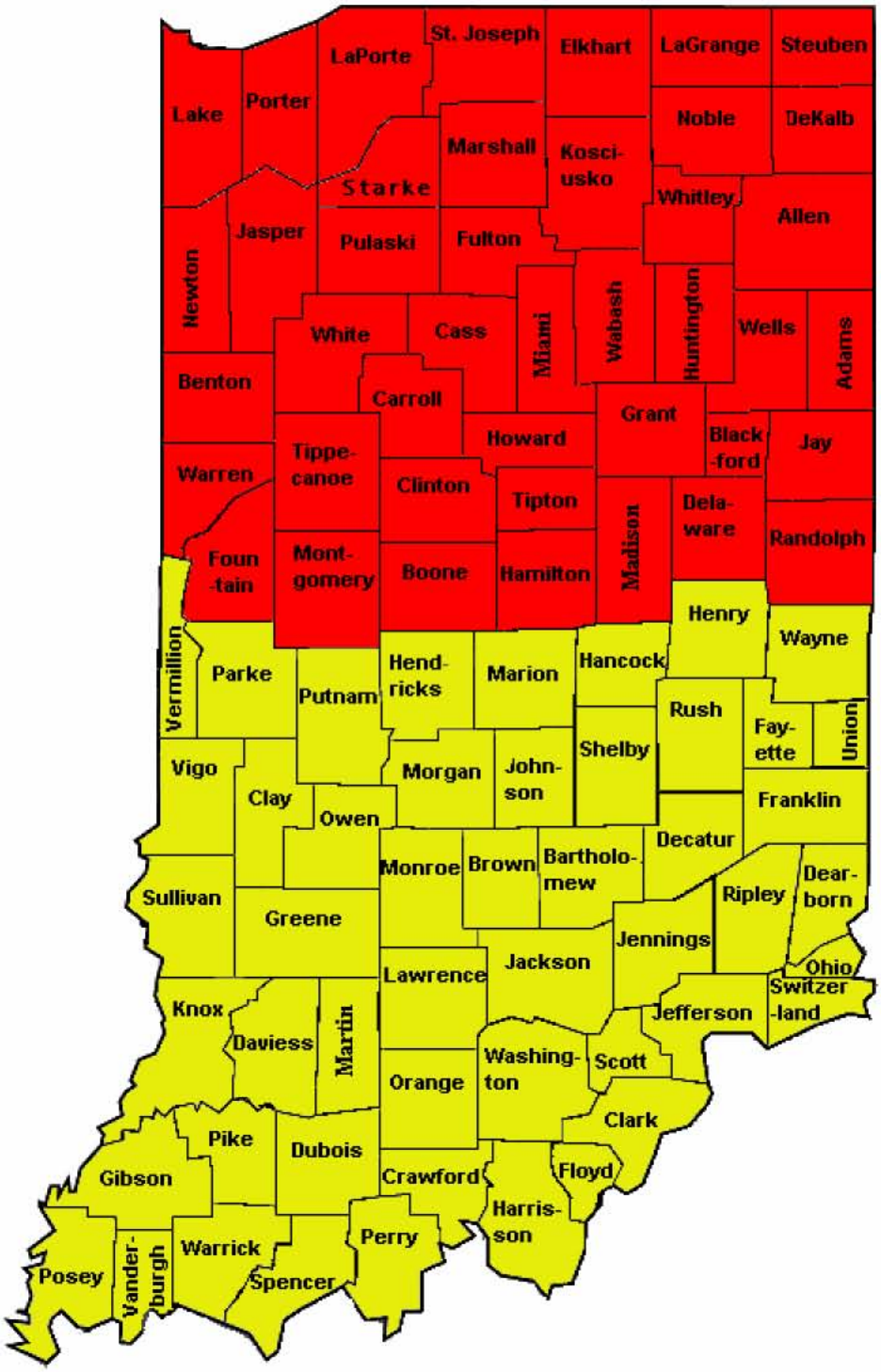
Explanation of Sample Drill Schedule

During each shift of staff, no more than a 3-month period elapses between some type of evacuation drill. For the first shift, various drills are planned and implemented with no more than 3 consecutive months between drills. Note: The drill is not required to be done within 90 days; rather, it should be completed at some point before the end of the third consecutive month after the first drill is completed. (See sample drill schedule on previous page.) For the second shift, a planned fire drill is conducted during January. An actual malfunction of a smoke alarm prompts staff to conduct and record a fire drill on March 25. The facility then adjusts its plans and conducts a tornado drill on June 3 to ensure that a drill is conducted within the third consecutive month. Other drills are planned and conducted to ensure that no more than 3 consecutive months elapse between drills. For the third shift, drills are planned and conducted with no more than a 3-consecutive-months period between any evacuation drill. An actual tornado warning results in an evacuation during the third shift in August, again prompting staff to record this as the response to a tornado drill. Note that a total evacuation of all persons served is planned and conducted once during the year on each shift.

Sample Drill Schedule

Month	First Shift	Second Shift	Third Shift
January		Planned Fire Drill: January 6	
February	Planned Fire Drill: February 3		Planned Fire Drill: February 16
March		Actual Smoke Alarm Malfunction (Used as Fire Drill): March 25	
April			
May	Planned Tornado Drill: May 12		Total Evacuation Drill: May 17
June		Planned Tornado Drill: June 3	
July			
August	Planned Hurricane Drill: August 5		Actual Tornado Warning (Used as Tornado Drill): August 1
September		Planned Total Evacuation Drill: September 21	
October			
November	Total Evacuation Drill: November 29		Planned Missing Person Drill: November 2
December		Planned Fire Drill: December 14	


Area 1
Judi Navarro
109 facilities
Area 2
Brenda Meredith
107 facilities
Area 3
Brenda Buroker
110 facilities
Area 4
Zetra Allen
31 facilities
Area 5
Karen Powers
119 facilities
Area 6
Pat Nicolaou
114 facilities
Lake
Porter
LaPorte
St. Joseph
Elkhart
LaGrange
Steuben
Noble
DeKalb
Marshall
Kosci-usko
Starke
Whitley
Allen
Jasper
Pulaski
Fulton
Newton
Miami
Wabash
Huntington
Wells
Adams
White
Cass
Benton
Carroll
Grant
Howard
Black-ford
Jay
Warren
Tippe-canoe
Clinton
Tipton
Madison
Dela-ware
Randolph
Foun-tain
Mont-gomery
Boone
Hamilton
Henry
Wayne
Vermillion
Parke
Putnam
Hend-ricks
Marion
Hancock
Rush
Fay-ette
Union
Vigo
Clay
Owen
Morgan
John-son
Shelby
Franklin
Decatur
Monroe
Brown
Bartholo-mew
Dear-born
Ripley
Sullivan
Greene
Jennings
Lawrence
Jackson
Ohio
Switzer-land
Knox
Daviess
Martin
Jefferson
Washing-ton
Scott
Orange
Clark
Pike
Dubois
Gibson
Crawford
Floyd
Harris-son
Perry
Warrick
Posey
Vander-burgh
Spencer
6 AREAS – 10/31/05
= Location of Supervisor



Area 8A
Wm. Chris
Greeney

North Team
T. Shebel - TL
R Wolf
K Craig
S. Eakright
R. Schwehn
R. Shackelford
Vacant PHNS 3
Vacant Med Sur 3
Vacant Med Sur 3

Area 8B
Steve
Corya

South Team
P. Chika – TL
M. Ficklin
J. McGinnis
D. Walton
M. Fisher
V. Kolb
J. A. Scott
R. Bauermeister

ICF/MRDD AREAS 11/07/05

HELPFUL WEB SITES

Access Indiana:
http://www.in.gov/

AdminaStar Federal:
http://www.adminastar.com

Centers for Medicare and Medicaid Services:
http://www.cms.hhs.gov/

CMS State Operations Manual:
http://www.cms.hhs.gov/SurveyCertificationGenInfo/

Family and Social Services Administration – Aging:
http://www.in.gov/fssa/elderly/

Family and Social Services Administration – Healthcare:
http://www.in.gov/fssa/healthcare/

Food Sanitation:
http://www.in.gov/isdh/regsvcs/foodprot/index.htm
Indiana Medicaid:
http://www.indianamedicaid.com/ihcp/index.asp

ICF-MR Federal Regulations:
http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/09_ICFMR.asp#TopOfPage

Indiana Secretary of State:
http://www.in.gov/sos/

Indiana State Department of Health:
http://www.in.gov/isdh/index.htm

NOTE: From drop down menu, select Health Care Regulatory Services, then select provider type (i.e., Comprehensive Nursing Facilities (Certified), Residential Care Facilities, etc.)

Indiana State Police:
http://www.in.gov/isp/

MDS Web Sites:
http://www.cms.hhs.gov/medicaid/mds20/ (includes links for new Section W)

National Provider Identifier Standard:
http://www.cms.hhs.gov/NationalProvIdentStand/

Nursing Facility Regulations:
http://www.cms.hhs.gov/GuidanceforLawsAndRegulations/12_NHs.asp#TopOfPage

Prevention and Control of Influenza
http://www.cdc.gov/mmwr/pdf/rr/rr5408.pdf

Prevention of Pneumococcal Disease
http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm

State Forms Online PDF Catalog:
http://www.state.in.us/icpr/webfile/formsdiv/index.html

Survey and Certification Letters
http://www.cms.hhs.gov/medicaid/survey-cert/letters.asp

US Government Printing Office:
http://www.gpo.gov/